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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,398	03/11/2005	Yukitsuka Kudo	740630-94	2825
22204	7590	09/26/2006	EXAMINER	
NIXON PEABODY, LLP 401 9TH STREET, NW SUITE 900 WASHINGTON, DC 20004-2128			CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/527,398

Applicant(s)

KUDO ET AL.

Examiner

Yong Chu

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35 are currently pending in the instant application and are subject to the following new lack of unity requirement. Per request by Applicant's representative Donald R. Studebaker on 14 September 2006, second restriction office action is prepared to further restrict the original claims because there are hundreds of prior arts are found based on the election of Group II elected by applicants on 13 July 2006. This second restriction will replace the previous office action dated on 15 June 2006.

Election/Restrictions

Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-35 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

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Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

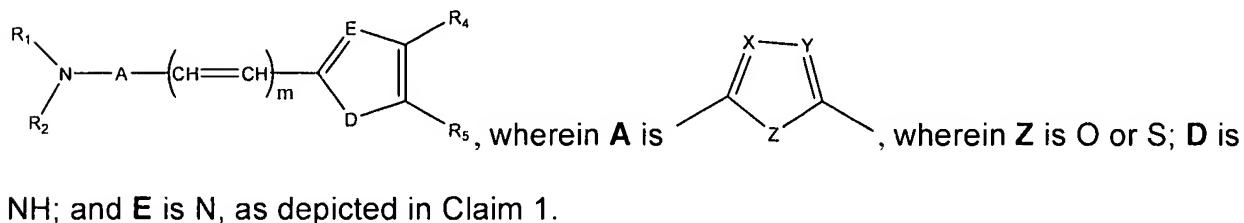
Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

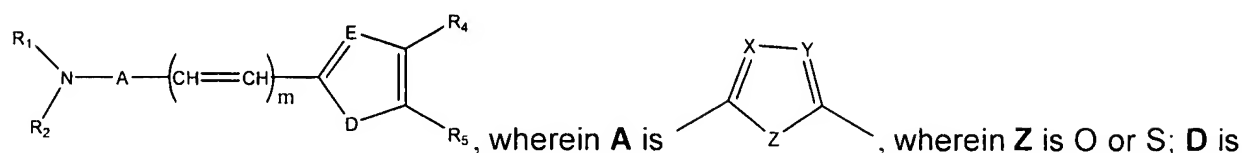
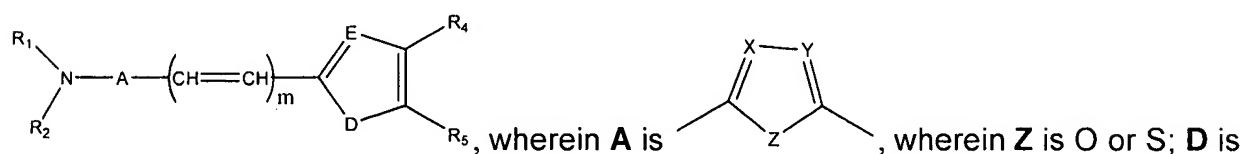
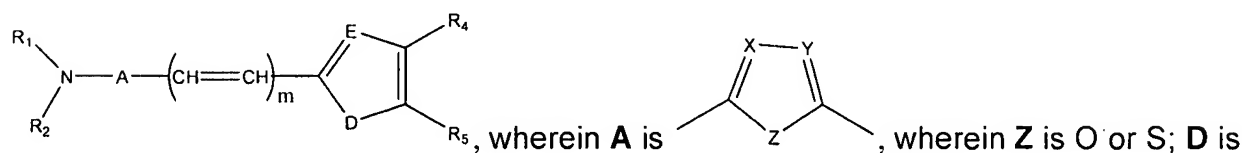
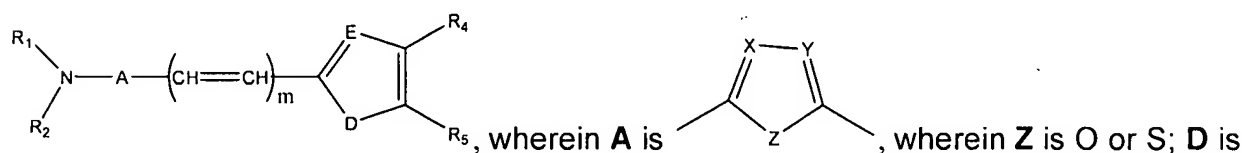
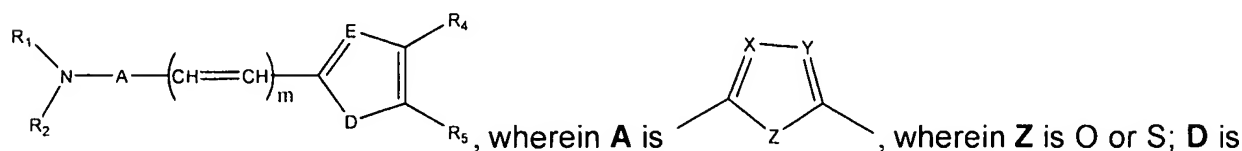
- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

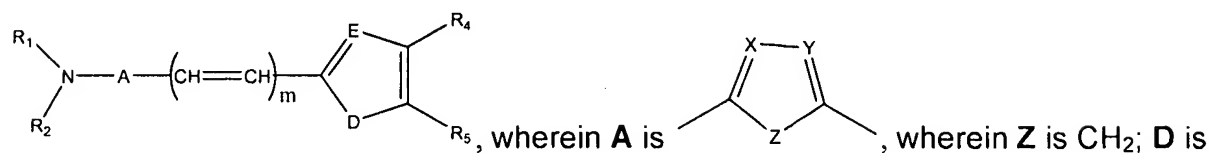
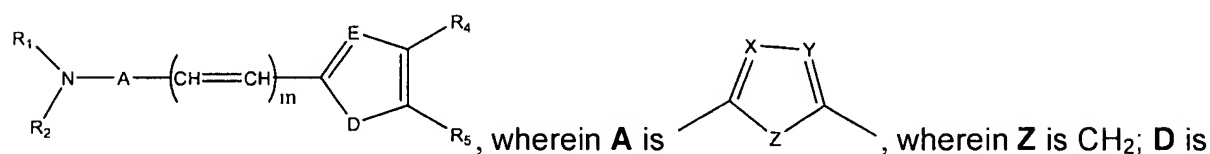
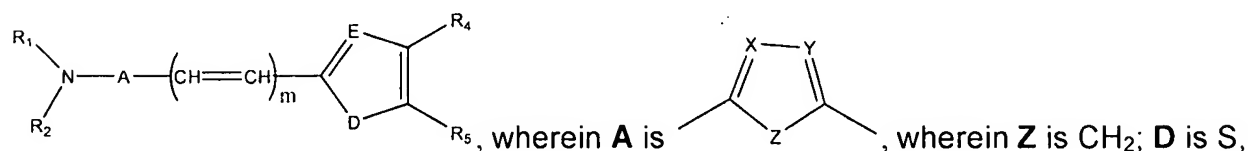
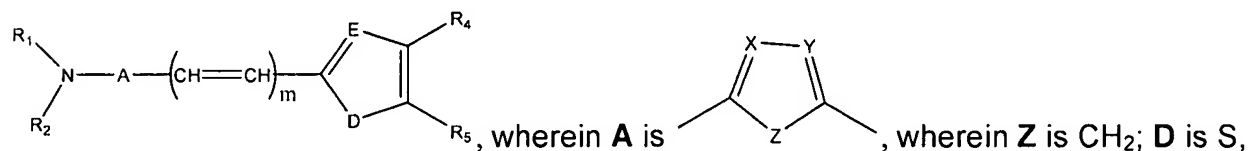
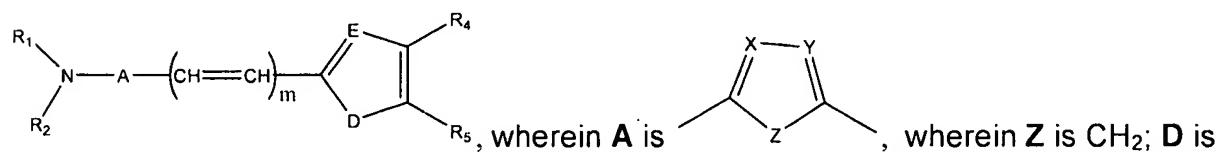
Group I: Claims 1-9, and 25 are drawn to products of formula (I)



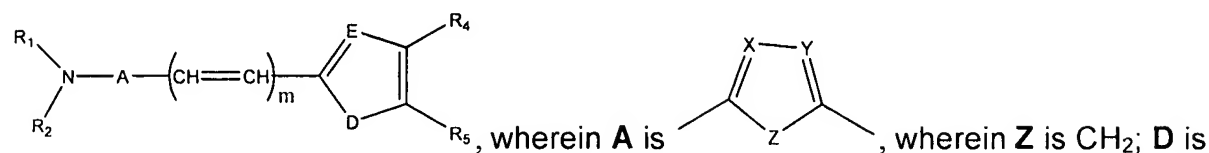
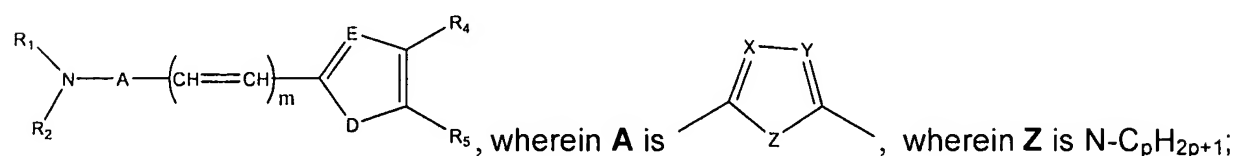
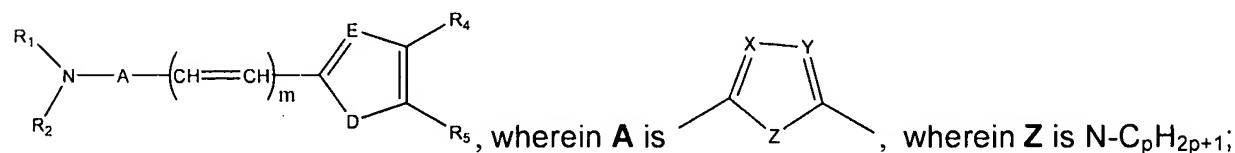
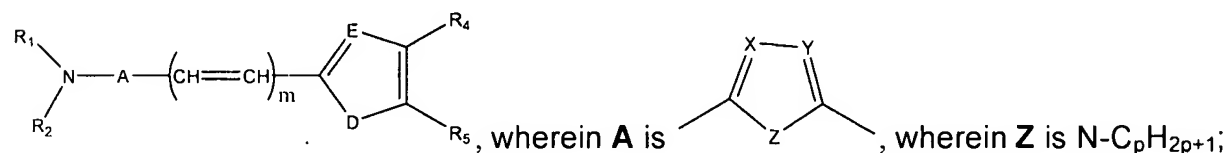
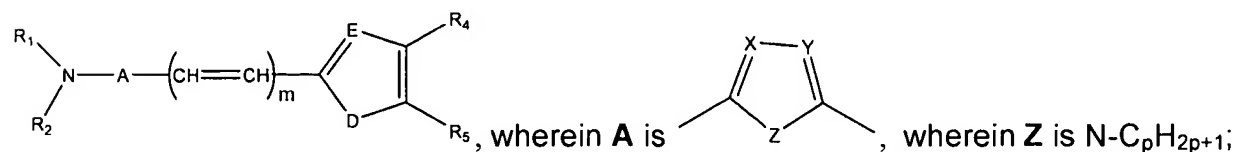
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Group II: Claims 1-9, and 25 are drawn to products of formula (I)NH; and **E** is CH, as depicted in Claim 1.Group III: Claims 1-9, and 25 are drawn to products of formula (I)S, or O; and **E** is N, as depicted in Claim 1.Group IV: Claims 1-9, and 25 are drawn to products of formula (I)S, or O; and **E** is CH, as depicted in Claim 1.Group V: Claims 1-9, and 25 are drawn to products of formula (I)CH=CH; and **E** is N, as depicted in Claim 1.Group VI: Claims 1-9, and 25 are drawn to products of formula (I)CH=CH; and **E** is CH, as depicted in Claim 1.

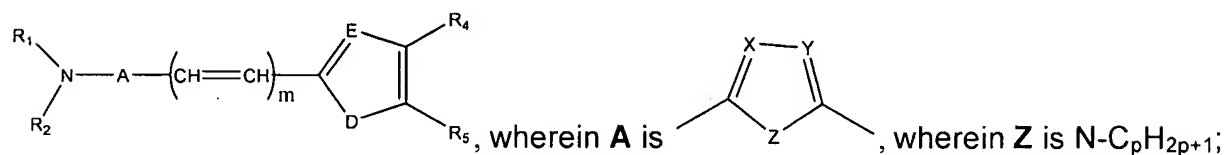
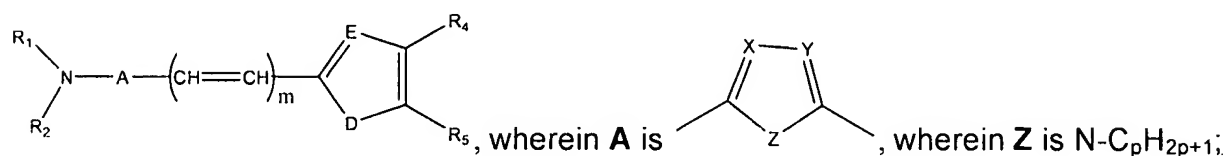
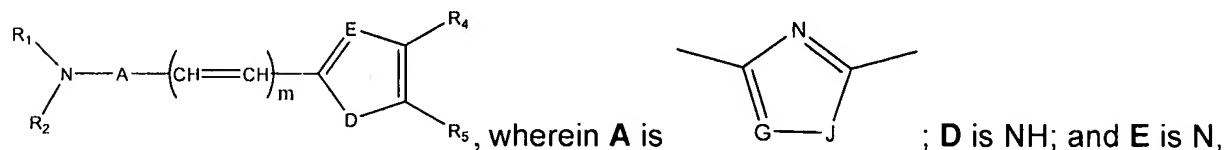
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Group VII: Claims 1-9, and 25 are drawn to products of formula (I)NH; and **E** is N, as depicted in Claim 1.Group VIII: Claims 1-9, and 25 are drawn to products of formula (I)NH; and **E** is CH, as depicted in Claim 1.Group IX: Claims 1-9, and 25 are drawn to products of formula (I)or O; and **E** is N, as depicted in Claim 1.Group X: Claims 1-9, and 25 are drawn to products of formula (I)or O; and **E** is CH, as depicted in Claim 1.Group XI: Claims 1-9, and 25 are drawn to products of formula (I)CH=CH; and **E** is N, as depicted in Claim 1.

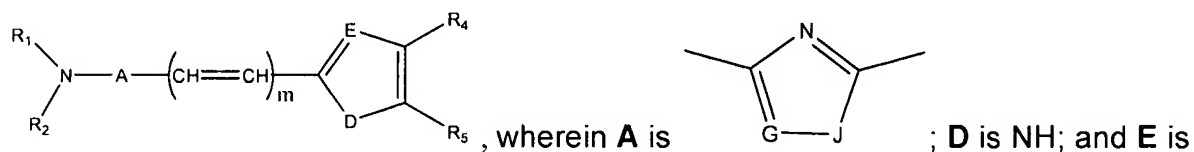
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Group XII: Claims 1-9, and 25 are drawn to products of formula (I)CH=CH; and **E** is CH, as depicted in Claim 1.Group XIII: Claims 1-9, and 25 are drawn to products of formula (I)**D** is NH; and **E** is N, as depicted in Claim 1.Group XIV: Claims 1-9, and 25 are drawn to products of formula (I)**D** is NH; and **E** is CH, as depicted in Claim 1.Group XV: Claims 1-9, and 25 are drawn to products of formula (I)**D** is S, or O; and **E** is N, as depicted in Claim 1.Group XVI: Claims 1-9, and 25 are drawn to products of formula (I)**D** is S, or O; and **E** is CH, as depicted in Claim 1.

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Group XVII: Claims 1-9 , and 25 are drawn to products of formula (I)**D** is CH=CH ; and **E** is **N**, as depicted in Claim 1.Group XVIII: Claims 1-9, and 25 drawn to products of formula (I)**D** is CH=CH ; and **E** is **CH**, as depicted in Claim 1.Group XIX: Claims 1-9, and 25 are drawn to products of formula (I)

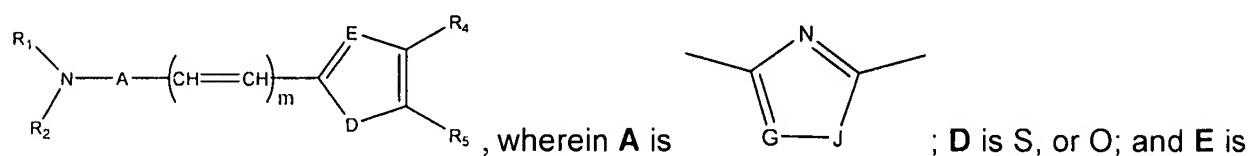
as depicted in Claim 1.

Group XX: Claims 1-9, and 25 are drawn to products of formula (I)**CH**, as depicted in Claim 1.

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Group XXI: Claims 1-9, and 25 are drawn to products of formula (I)

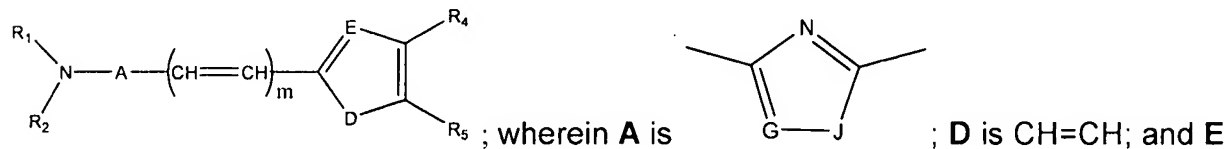
N, as depicted in Claim 1.

Group XXII: Claims 1-9, and 25 are drawn to products of formula (I)

CH, as depicted in Claim 1.

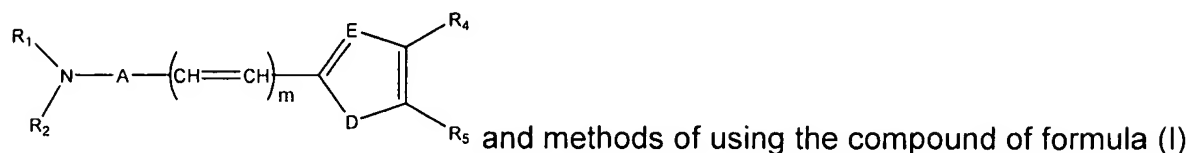
Group XXIII: Claims 1-9, and 25 are drawn to products of formula (I)

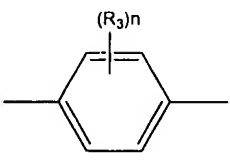
wherein **A** is ; **D** is CH=CH; and **E** is N, as depicted in Claim 1.

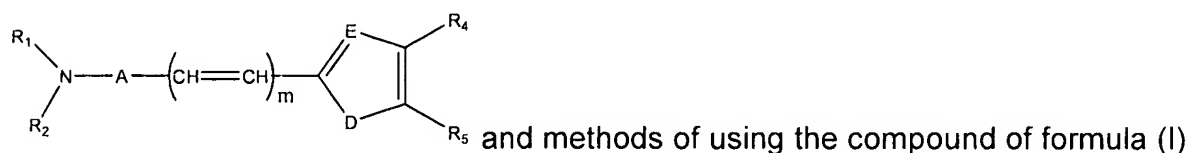
Group XXIV: Claims 1-9, and 25 are drawn to products of formula (I)

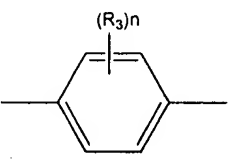
is CH, as depicted in Claim 1.

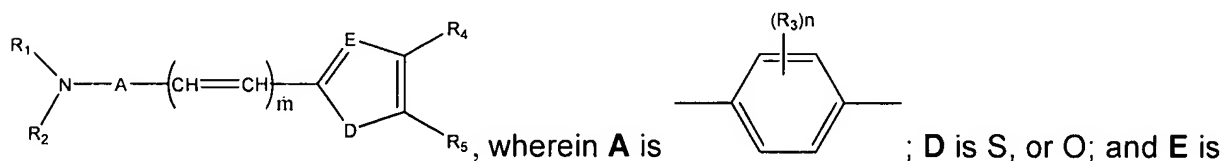
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Group XXV: Claims 1-9, and 25 are drawn to products of formula (I)

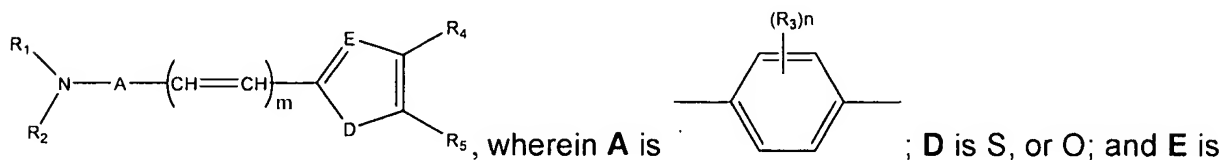
wherein **A** is ; **D** is NH; and **E** is N, as depicted in Claim 1.

Group XXVI: Claims 1-9, and 25 are drawn to products of formula (I)

wherein **A** is ; **D** is NH; and **E** is CH, as depicted in Claim 1.

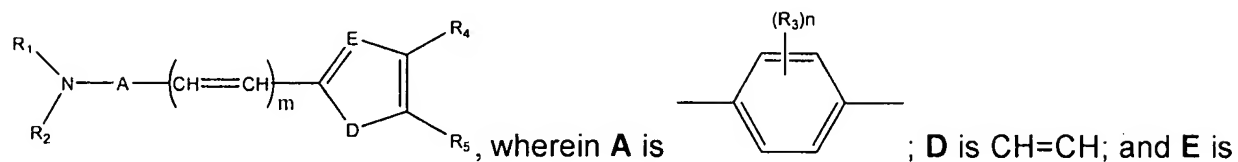
Group XXVII: Claims 1-9, and 25 are drawn to products of formula (I)

N, as depicted in Claim 1.

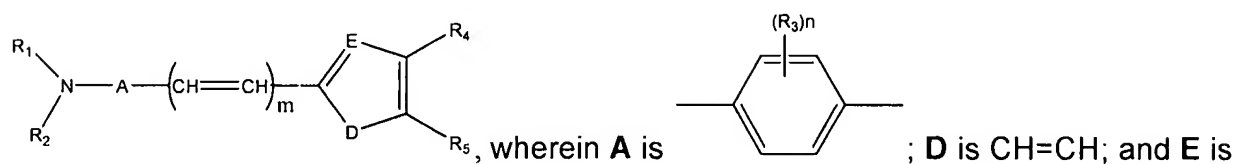
Group XXVIII: Claims 1-9, and 25 are drawn to products of formula (I)

CH, as depicted in Claim 1.

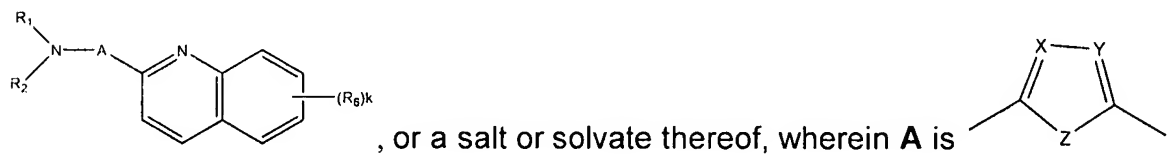
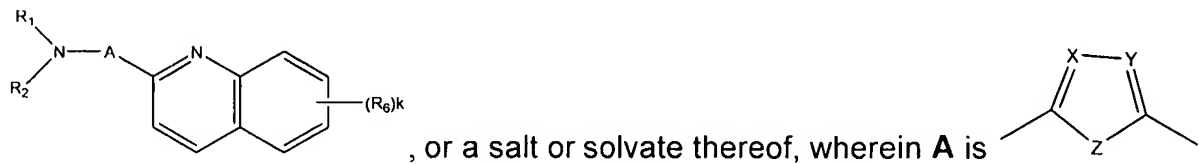
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Group XXIX: Claims 1-9, and 25 are drawn to products of formula (I)

N, as depicted in Claim 1.

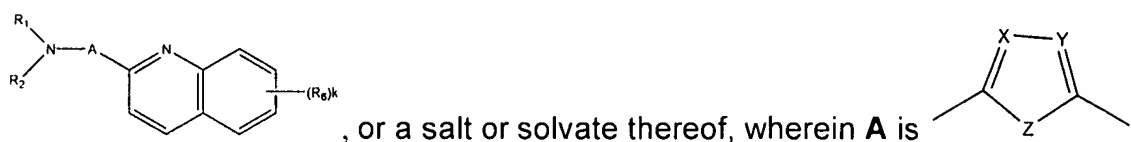
Group XXX: Claims 1-9, and 25 are drawn to products of formula (I)

CH, as depicted in Claim 1.

Group XXXI: Claims 17 and 18 are drawn to products of formula (II)wherein **Z** is O or S, as depicted in Claim 1.Group XXXII: Claims 17 and 18 are drawn to products of formula (II)wherein **Z** is CH₂, as depicted in Claim 1.

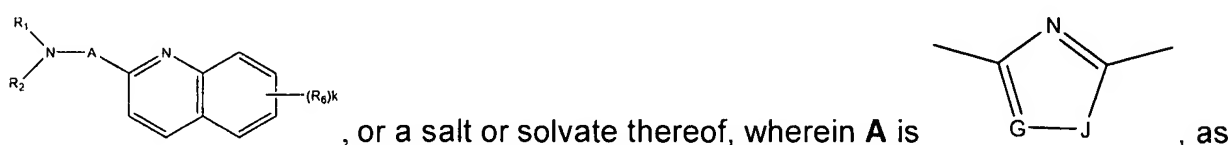
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Group XXXIII: Claims 17 and 18 are drawn to products of formula (II)



wherein **Z** is $\text{N-C}_p\text{H}_{2q+1}$, as depicted in Claim 1.

Group XXXIV: Claims 17 and 18 are drawn to products of formula (II)



depicted in Claim 1.

Group XXXV: Claims 10, 11, and 12 are drawn to a composition or a kit for the imaging diagnosis of a disease in which amyloid β -protein accumulates, comprising a compound according to claims 1 or 4.

Group XXXVI: Claims 13, and 14 are drawn to a composition for staining senile plaques, comprising a compound according to claims 2 or 13.

Group XXXVII: Claims 15, and 16 are drawn to a pharmaceutical composition for the treatment and/or prophylaxis of a disease in which amyloid β -protein accumulates, comprising a compound according to claims 1.

Group XXXVIII: Claims 19 and 21 are drawn to a method for the prophylaxis and/or treatment of a disease in which amyloid β -protein accumulates, comprising a compound, or a pharmaceutical acceptable salt or solvate thereof, according to claim 1.

Group XXXIX: Claim 20 is drawn to a method for the diagnosis of a disease in which amyloid β -protein accumulates, comprising a compound, or a pharmaceutical acceptable salt or solvate thereof, according to claim 1.

Group XXXX: Claims 22-24 are drawn to a method for detecting or staining neurofibrillary tangles, which comprises employing a compound according to claim 17.

Group XXXXI: Claim 26 is drawn to a composition kit for the imaging diagnosis of a conformational disease, comprising a compound, or salt or solvate thereof, according to claim 1.

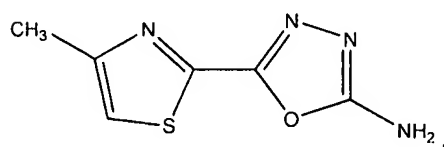
Group XXXXII: Claim 27 is drawn to a pharmaceutical composition for the prophylaxis and/or treatment of a conformational disease, comprising a compound, or salt or solvate thereof, according to claim 1.

Group XXXXIII: Claims 28 and 29 are drawn to a method for the diagnosis of a conformational disease, comprising a compound, or a pharmaceutical acceptable salt or solvate thereof, according to claim 1.

Group XXXXIV: Claims 30 and 31 are drawn to a method for the prophylaxis and/or treatment of a conformational disease, comprising a compound, or a pharmaceutical acceptable salt or solvate thereof, according to claim 1.

Group XXXXV: Claims 32-35 are drawn to a precursor compound for synthesizing a compound according to any one of claim 1.

There is no core component moiety common to **Groups I-XXXXV**. However, there are formula (I), and (II) full of symbols (i.e. E,D,A,X,Y,Z,...), which are different in core structure. There are hundreds prior arts have been found. As an example, Kempter et al., Zeitschrift Fuer Chemie (1970), 10(12), 460-2, disclose a compound



, which reads on the instant claims. Thus, the instant

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claim 1 do not possess special technical feature. Therefore, claims 1-35 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Due to the numerous and widely divergent variables in the compound of formula (I), it would be impossible to list all groups under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product or a method of use of said product) by identifying another specific embodiment, i.e. another value for m. R1-R4, X, Y, G, J, not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art, as well as lack a core structure which can be seen by two formulas (I) and (II) in the same application.

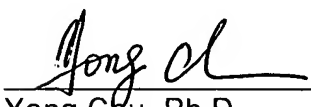
Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

Telephone Inquiry


Any inquiry concerning this communication or earlier communications from the examiner should be directed Yong Chu whose telephone number 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Yong Chu, Ph.D.
Patent Examiner, AU 1626



Joseph McKane
Supervisory Patent Examiner
AU 1626